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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/021,403	12/12/2001	Robert J. Schwartz	108328.00031	3652
7590 10/20/2003			EXAMINER	
T. Ling Chwang Jackson Walker L.L.P. Suite 600 2435 N. Central Expressway Richardson, TX 75080			SHUKLA, RAM R	
			ART UNIT	PAPER NUMBER
			1632	

DATE MAILED: 10/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/021,403	SCHWARTZ ET AL.	
	Examiner	Art Unit	
	Ram R. Shukla	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-136 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-136 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-136 are pending.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-13, 76-88, drawn to a method of improving or enhancing growth in an offspring in a female animal by administering to the cells of the female animal a vector comprising a promoter, a nucleotide sequence and a 3' untranslated region, classified in class 514, subclass 44.
- II. Claims 1, 14, 15, 76, 89, 90, drawn to a method of improving or enhancing growth in an offspring in a female animal by administering to the cells of the female animal a vector comprising a promoter, a nucleotide sequence and a 3' untranslated region and further administering a ligand fro a growth hormone secretagogue receptor, classified in class 514, subclass 44.
- III. Claims 16-28, drawn to a method of increasing growth hormone level in an offspring in a female animal by administering to the cells of the female animal a vector comprising a promoter, a nucleotide sequence and a 3' untranslated region, classified in class 514, subclass 44.
- IV. Claims 16, 29 and 30, drawn to a method of increasing growth hormone level in an offspring in a female animal by administering to the cells of the female animal a vector comprising a promoter, a nucleotide sequence and a 3' untranslated region and further administering a ligand fro a growth hormone secretagogue receptor, classified in class 514, subclass 44.
- V. Claims 31-43, drawn to a method of increasing lean body mass in an offspring in a female animal by administering to the cells of the female animal a vector comprising a promoter, a nucleotide sequence and a 3' untranslated region, classified in class 514, subclass 44.

- VI. Claims 31, 44, 45, drawn to a method of increasing lean body mass in an offspring in a female animal by administering to the cells of the female animal a vector comprising a promoter, a nucleotide sequence and a 3' untranslated region and further administering a ligand from a growth hormone secretagogue receptor, classified in class 514, subclass 44.
- VII. Claims 46-58, drawn to a method of increasing IGF-I levels in an offspring in a female animal by administering to the cells of the female animal a vector comprising a promoter, a nucleotide sequence and a 3' untranslated region, classified in class 514, subclass 44.
- VIII. Claims 46, 59, 60, drawn to a method of increasing IGF-I levels in an offspring in a female animal by administering to the cells of the female animal a vector comprising a promoter, a nucleotide sequence and a 3' untranslated region and further administering a ligand from a growth hormone secretagogue receptor, classified in class 514, subclass 44.
- IX. Claims 61-73, drawn to a method of increasing feed efficiency in an offspring in a female animal by administering to the cells of the female animal a vector comprising a promoter, a nucleotide sequence and a 3' untranslated region, classified in class 514, subclass 44.
- X. Claims 61, 74, 75, drawn to a method of increasing feed efficiency in an offspring in a female animal by administering to the cells of the female animal a vector comprising a promoter, a nucleotide sequence and a 3' untranslated region and further administering a ligand from a growth hormone secretagogue receptor, classified in class 514, subclass 44.
- XI. Claims 91-103, 106, drawn to a method of increasing the ratio of somatotrophs to other hormone producing cells in a pituitary gland in an offspring in a female animal by administering to the cells of the female animal a vector comprising a promoter, a nucleotide sequence and a 3' untranslated region, classified in class 514, subclass 44.

- XII. Claims 91, 104, 105, drawn to a method of increasing the ratio of somatotrophs to other hormone producing cells in a pituitary gland in an offspring in a female animal by administering to the cells of the female animal a vector comprising a promoter, a nucleotide sequence and a 3' untranslated region and further administering a ligand from a growth hormone secretagogue receptor, classified in class 514, subclass 44.
- XIII. Claims 107-119, drawn to a method of delaying birth of an offspring in a female animal by administering to the cells of the female animal a vector comprising a promoter, a nucleotide sequence and a 3' untranslated region, classified in class 514, subclass 44.
- XIV. Claims 107, 120, 121, drawn to a method of delaying birth of an offspring in a female animal by administering to the cells of the female animal a vector comprising a promoter, a nucleotide sequence and a 3' untranslated region and further administering a ligand from a growth hormone secretagogue receptor, classified in class 514, subclass 44.
- XV. Claims 122-134, drawn to a method of increasing milk production in an animal by administering to the cells of the animal a vector comprising a promoter, a nucleotide sequence and a 3' untranslated region, classified in class 514, subclass 44.
- XVI. Claims 122, 135, 136, drawn to a method of increasing milk production in an animal by administering to the cells of the animal a vector comprising a promoter, a nucleotide sequence and a 3' untranslated region and further administering a ligand from a growth hormone secretagogue receptor, classified in class 514, subclass 44.

3. Inventions of the groups I-XV are related as different processes of use a product. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP

§ 806.05(h)). In the instant case, a vector comprising a promoter, a nucleic acid sequence and a 3' untranslated region, is used for increasing growth, growth hormone levels, lean body mass, IGF-1 level, feed efficiency, ratio of somatotrophs to other hormone-producing cells in pituitary gland and for delaying birth in an offspring and for increasing milk production in an animal. It is noted that since all the treatment conditions are distinct, the search for relevant art for one will not be coextensive with others. Additionally, any nucleic acid will not treat all the conditions recited in different inventions. Therefore, all the methods will require separate search in the patent and non-patent literature.

4. Inventions of the groups I and II, III and IV, V and VI, VII and VIII, IX and X, XI and XII, XIII and XIV, XV and XVI are related as subcombination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the subcombination of groups I, III, V, VII, IX, XI, XIII and XV do not require the particulars of the ligand for a growth hormone secretagogue receptor for practicing the methods. Additionally, the ligand can be used for other purposes, for example for blocking receptor functions.

5. Because these inventions are distinct for the reasons given above, have acquired a separate status in the art shown by their recognized divergent subject matter, and because each invention requires a separate, non-coextensive search, restriction for examination purposes as indicated is proper.


Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if

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one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ram R. Shukla whose telephone number is (703) 305-1677. The examiner can normally be reached on Monday through Friday from 7:30 am to 4:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051. The fax phone number for TC 1600 is (703) 703-872-9306. Any inquiry of a general nature, formal matters or relating to the status of this application or proceeding should be directed to the William Phillips whose telephone number is (703) 305-3413.


RAM R. SHUKLA, PH.D.
PRIMARY EXAMINER

Ram R. Shukla, Ph.D.
Primary Examiner
Art Unit 1632